Development of a Prehabilitation Multimodal Supportive Care Interventions for Men and Their Partners Before Radical Prostatectomy for Localized Prostate Cancer

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Published in:
Cancer Nursing

DOI:
10.1097/NCC.0000000000000618

Publication date:
2018

Document Version
Peer reviewed version

Author Accepted Mansucript version of Paterson, C., Primeau, C., Pullar, I., & Nabi, G. (2018).
Development of a Prehabilitation Multimodal Supportive Care Interventions for Men and Their Partners Before Radical Prostatectomy for Localized Prostate Cancer. Cancer Nursing.
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Introduction

Radical prostatectomy (RP) is a common and effective treatment for localized prostate cancer (PCa), with a 15-year survival rate 3. However RP, is associated with significant adverse side effects, such as urinary incontinence, sexual dysfunction, and reduced physical function that negatively affects health-related quality of life (HRQOL) and psychological well-being 4-8. Existing interventions have typically focused on the urological side effects of urinary incontinence and sexual dysfunction through pelvic floor muscle exercises and/or phosphodiesterase-5 inhibitors, and psychotherapy commonly employed for psychological adjustments, all in the post-operative period6,7,9.

To optimise the overall RP experience for patients, an important clinical question revolves around when the most opportune time is to introduce recovery-optimizing behaviors10. The post-operative period may be less than ideal due to self-management concerns related to perturbing the healing process, and patients are anxious in awaiting results of Prostate Specific Antigen (PSA) and histopathology. Instead, an emerging field of research describes the role of pre-operative strategies to improve treatment tolerance, recovery and risk stratified pathways of follow-up care. The pre-operative period may be more physically and emotionally salient for patients and families by capitalizing on: 1) better general physical condition of the patient (compared to the acute post-operative period), 2) surgical wait-list times, 3) a ‘teachable moment’ for the patient that accompanies the need for major surgery, and 4) to prepare patients and families psychologically for the impending surgery and recovery11. Ultimately, it is hypothesized that the pre-operative period may be the optimal time to invest into the modifiable

supportive care factors and strategies that contribute to peri- and post-operative health, see (Figure 1) 10,12 .

Studies routinely report that patients who are physically active and fit recover more quickly, have fewer peri-operative complications, and experience better convalescence compared with patients who are less physically active and fit10. Cancer pre-habilitation is defined as a process on the continuum of care that occurs between the time of a cancer diagnosis and the time prior to the beginning of acute treatment12. Pre-habilitation includes physical and psychological assessments that establish a baseline functional level, identifies impairments, and provides targeted interventions aimed to improve a patient's health to reduce the incidence and the severity of current and future impairments9,10,12-14. In a surgical setting, pre-operative physical and/or psychological conditioning aims to increase body and mind reserves to prevent the inevitable decline in physical and psychological well-being in the post-operative period 12. Recently several published studies have described numerous pre-habilitation benefits to post-operative well-being across a variety of cancer populations 15, including improvements in physical function in cancer patients undergoing colorectal surgery 16, and bladder cancer 17. However, no pilot testing of pre-habilitation multimodal supportive care interventions have been conducted in men affected by localized prostate cancer prior to radical therapy 9 .

The need for optimizing “timely” and “person-centred” interventions is informed by a series of research studies, including systematic reviews 18-21. Men affected by prostate cancer may experience long-term treatment side effects (e.g., incontinence, sexual dysfunction) that challenge the patient's sense of masculinity and identity, and reduce mental and social well-

being 6,8,9,18,22,23. Men have reported that they can experience a lack of awareness of available resources 24 and men have reported unmet informational needs around the self-management of side-effects 19,21, a lack of awareness of appropriate sign-posting to healthcare professionals 18,25, and a lack of dietary and physical exercise advice 26. Moreover, there is increasing evidence to acknowledge that couples affected by prostate cancer report an erosion in spousal bond, reduced couple communication 22 and spouse/partner isolation 23.

To date, pre-habilitation interventions in cancer care have typically focussed on exercise intervention programmes27 as a unimodal approach. Moreover, existing pre-habilitation studies have not addressed the supportive care needs of the partner10. More recently, studies have concluded that a multimodal approach that incorporates both physical and psychological pre-habilitation interventions may be more effective than a unimodal approach10.

To the best of our knowledge, this is the first study to test the feasibility and acceptability of a pre-habilitation multimodal supportive care intervention for men opting for RP for localized PCa and include their partner to inform a future pilot Randomized Controlled Trial (RCT).

Methods

Patients and Methods

Setting

The healthcare provision of National Health Service (NHS) Tayside in Scotland serves a geographical area which consists of predominantly white ethnicity, of an urban and rural

population of more than 405,721 individuals based on mid-year 2011 population estimates published by the General Register Office for Scotland. The study had institutional approval (CSAppGN021211).

Participants

Thirty-four patients who opted for RP for localized PCa and their partner (19) were identified and recruited into the study. Men treated by salvage radical prostatectomy and/or receiving neoadjuvant/adjuvant therapy were excluded. The study was undertaken in NHS Tayside, Scotland from January 2017 to July 2017.

Pre-habilitation Intervention

The intervention was developed using the Medical Research Council Framework for complex interventions 28 and the six steps in quality intervention development (6SQuID) 29. The intervention and associated materials were developed in consultation with multidisciplinary healthcare experts including patients' representatives. The pre-habilitation intervention comprised of three main components: 1) informational materials, 2) pelvic floor exercise instruction delivered by an experienced advanced pelvic floor physiotherapist, and 3) an evidence-based self-management seminar. Men and their partners participated in the multimodal pre-habilitation intervention 4 weeks prior to RP.

Informational materials

Participants were provided with a custom-made evidence-based self-management booklet entitled "A Prostate Cancer Guide to Thrivership: Men it is time to Thrive" (Supplementary

Information). The information booklet included the following topics: how to self-care, managing the side-effects of prostate surgery, relationships and sexual well-being, nutrition and exercise, healthy lifestyle approaches and community based support resources.

Pelvic floor exercise instruction

Participants were provided with a pelvic floor prescription at the time of the seminar, which begin with education on the pelvic anatomy, and instructions on how to perform pelvic floor muscles exercises by an advanced senior pelvic physiotherapist (I.P.). The pelvic floor prescription included a gradual increase in repetitions from 60 per day during weeks 1–2, 120 per day during weeks 2–3, and 180 per day until the surgical date. The total number of repetitions were divided equally between the rhythmic contractions (contract and relax over one second) and the sustained contractions (contract and hold for up to 10 seconds). Participants were also advised to contract the pelvic floor muscles when they coughed, sneezed, or lifted on physical exertion. Participants were instructed to contract with their maximum effort during all repetitions.

Group-based seminar

The evidence-based self-management seminar (1.5 hours) included the following topics: 1) introduction to radical prostatectomy and potential side-effects, 2) self-managing side-effects, 3) managing emotions and mind changes, 4) erectile dysfunction and relationships, 5) nutrition and exercise, 6) finance and benefits, 7) relaxation and stress management, and 8) sign-posting to community based services and open question session. The seminar was led by an experienced senior prostate cancer specialist nurse, advanced pelvic floor physiotherapist and a

trained counsellor, underpinned by the Prostate Cancer Model of Consultation20. The intervention was delivered at Maggie's Cancer Care Centre.

Outcomes

All participants completed the following patient reported outcome measures: the Supportive Care Needs Survey (SCNS-SF34) which is a multidimensional self-report questionnaire that evaluates 34 patient needs that fall under the following five domains: health system and information, psychological, physical and daily living, patient care and support, and sexuality 1. The supportive care needs survey (SCNS) is a self-administered instrument, face and content validity are found to be high, and Cronbach alpha coefficients ranged 0.87 – 0.97 for all 5 scales. The instrument assesses whether issues of need have been experienced, which of the issues experienced remain unmet needs, and the magnitude of such needs. Patients and partner/caregivers were also invited to complete a qualitative Feedback Questionnaire to evaluate the usefulness of the pre-habilitation multimodal supportive care intervention, an instrument previously used in the evaluation of multimodal supportive care interventions in prostate cancer patients 2.

Analysis

All analyses were conducted in SPSS Statistics for Windows version 21.0 (IBM Corp., SPSS for windows, Armonk, NY). Descriptive statistics were used to summarize outcome measures. Prior to the analysis, variables were examined for accuracy of data entry and missing values. Basic exploratory statistical analysis of indicative findings was undertaken to evaluate the usefulness of the intervention to inform a future pilot RCT study.

One of the authors (CP) coded all the qualitative Feedback Questionnaires, and coding was subsequently verified by a second and a third author, when needed, to ensure a close match. Framework analysis was used to examine commonalities and differences within and between the qualitative verbatim. Broad themes were identified, and an electronic matrix display (in Microsoft Excel®), which included original links to the data, was used to keep a transparent account of how themes were derived.

Results

Of the 37 patients invited to participant in the pre-habilitation seminar, 34 men took part (91.9%). Two men were unable to participate due to having their surgical date of RP moved, and one man declined participation as he did not perceive this as being helpful for him. Prior to radical surgery men experienced a range of supportive care needs as measured by the Supportive Care Needs Survey areas of most need were related to feelings of anxiety (n7) and depression (n7), uncertainty for the future (n9), learning to feel in control (n8), worries about changes in sexual relationships (n10), and fear of death and dying (n4), see (Table). Of the 19 partners only five completed the SCNS-SF34 questionnaire. The main reason for non-completion was that partners articulated that the SCNS-SF34 was not applicable to them, they expressed that the SCNS-SF34 was aimed to explore experiences for people who have been diagnosed with a cancer. Of the five partners who completed the SCNS-34 reported unmet needs related to fear of cancer spreading (n2), uncertainty for the future (n3), concerns of changes in sexual relationships (n5), and the need for information and explanations about tests (n2).

The pre-habilitation seminar was well attended and demonstrated acceptability (91.9%). Participants documented open comments captured in the pre-habilitation intervention Feedback Questionnaire which related to several themes. This identified that information and education was particularly important for men and their partner, and the importance of having an opportunity to have an open dialogue with other patients, partner and healthcare professionals prior to radical therapy:

"Open comments from the floor (other participants) helpful" and "it was a very useful afternoon, and to be able to ask specific questions regarding personal problems or issues to specialist healthcare professionals was invaluable".

The multi-disciplinary approach to delivering the pre-habilitation multimodal self-management intervention was perceived as beneficial and alleviated concerns of embarrassment, particularly around topics of sexual rehabilitation and urinary incontinence:

"Very useful, informative and supportive, very impressed with the quality of the information" and *"it was very professional but in a friendly, easy to understand manner which raised a smile in what could have been a very daunting time, and embarrassing for our partners".*

Partner perceived benefit in participating in the pre-habilitation seminar through developing a better understanding of how they can support their husbands before and following their impending radical prostatectomy:

"I found it all very helpful and glad that I have been able to support my husband and meet the staff looking after him" and "I learnt a lot more in how I can help to support my husband".

Qualitative feedback in relation to the pre-habilitation multimodal intervention was perceived as overall helpful and informative, Figure 2. Most participants (n52, 98.1%) found the time allocated to each pre-habilitation subject was adequate in the seminar. Moreover, (n52, 98.1%) did not experience any inconvenience in participating in the intervention in relation to travelling time, time away from work, lack of motivation to participate or not wanting to meet other people.

Discussion

This study makes an important contribution to the understanding of the role of a pre-habilitation multimodal supportive care intervention in addressing the supportive care needs of men affected by localized prostate cancer prior to radical prostatectomy and the needs of their partners. Pre-habilitation, or pre-operative conditioning aims to improve psychological and physiological capacity to support patients to withstand the stress of the surgical event and enhance recovery 13. Up until now, pre-habilitation interventions have been unimodal and have typically focused on exercise based interventions with a dearth of pre-habilitation psychological intervention in prostate cancer14. This intervention development study has demonstrated acceptability of a multimodal pre-habilitation intervention for men opting for RP and their partners.

Our study is the first to capture data on the experience of supportive care needs of men prior to radical prostate surgery and their partners. Existing research has typically focussed on the post-treatment patient trajectory 21,24,30. Men experienced a range of unmet supportive care needs prior to radical surgery related to psychological well-being, coping with the uncertainty of the future, concerns about changes in sexual relationships, fear of death and dying and fear of the cancer spreading. Research evidence has identified that the supportive care concerns of men following radical therapy are related to psychological and sexual needs which continue post treatment phase and into survivorship 18,21,30,31. Consequently, existing evidence underscores the need for further multimodal interventions prior to radical therapy and into survivorship to optimise recovery and overall quality of life.

Prostate cancer and its treatment not only affect the individuals with the illness but can have a significant impact on family members as well. In addition to coping with the diagnosis and uncertainty of the disease, partners often have added caregiver responsibilities and supportive care needs of their own 32. Galbraith et al. 33 have demonstrated the strong interrelationship between patient and partner quality of life for couples experiencing prostate cancer, indicating mutuality in response to the disease and its treatment, and a compelling argument to consider both the patient and his partner throughout pre-habilitation programmes in the future. This study provides data to support the acceptability and feasibility of this intervention to inform a future pilot RCT study.

Our study has limitations that deserve a mention. First, the aim of this study was to develop a pre-habilitation multimodal intervention to inform a future pilot RCT study and therefore, our study has focused on the experiences of patients and their spouses before RP, and limits the assessment of persistent longitudinal effects. Future research should examine the prostate cancer dyads' experience of supportive care needs, coping, quality of life, self-management self-efficacy and psychological distress over this disease trajectory 34. If these variables have a long-term predictive effect on quality of life and supportive care needs, such data can be used to inform early identification of couples that may be vulnerable for experiencing increased distress. We had missing data in relation to the SCNS-SF34 for partners. Partners reported that this questionnaire was designed for patients who have been diagnosed with a cancer, not necessarily themselves as loved ones or relatives to explore their needs per se. Given this limitation, future research is needed to explore and develop standardised instruments with

demonstrated reliability and validity to assess the supportive care needs of partners/loved ones affected cancer.

Conclusion

This study adds to the pre-habilitation literature and provides data that acknowledges that our novel multimodal supportive care intervention is feasible and beneficial for the prostate cancer dyad. A future pilot RCT study is needed to provide sufficient evidence on the short- and long-term physical and psychological outcomes as well as cost-effectiveness. Pre-habilitation multimodal interventions has the potential to empower patients and partners affected by localized prostate cancer to take responsibility for their recovery and has the potential to inform appropriate risk stratified pathways of follow-care in the future.

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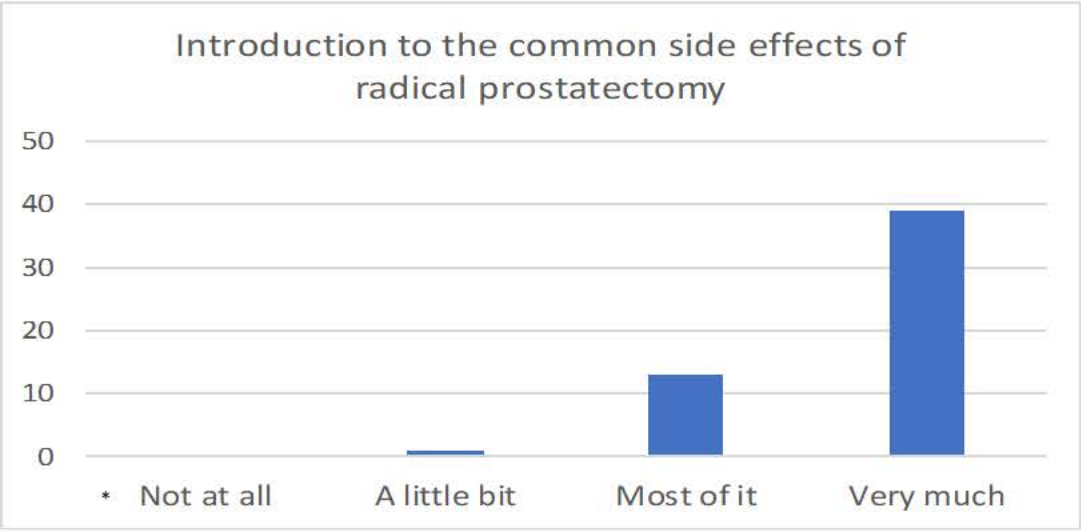

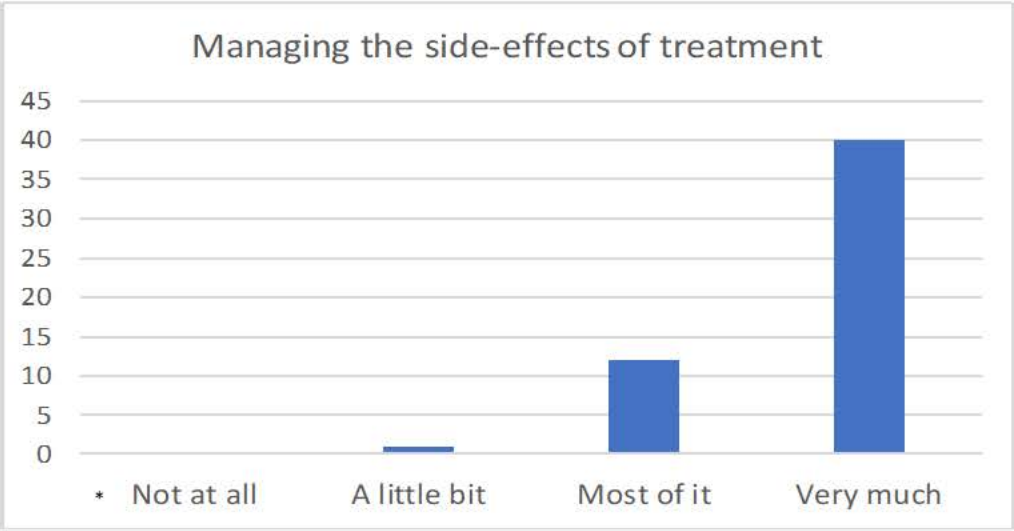

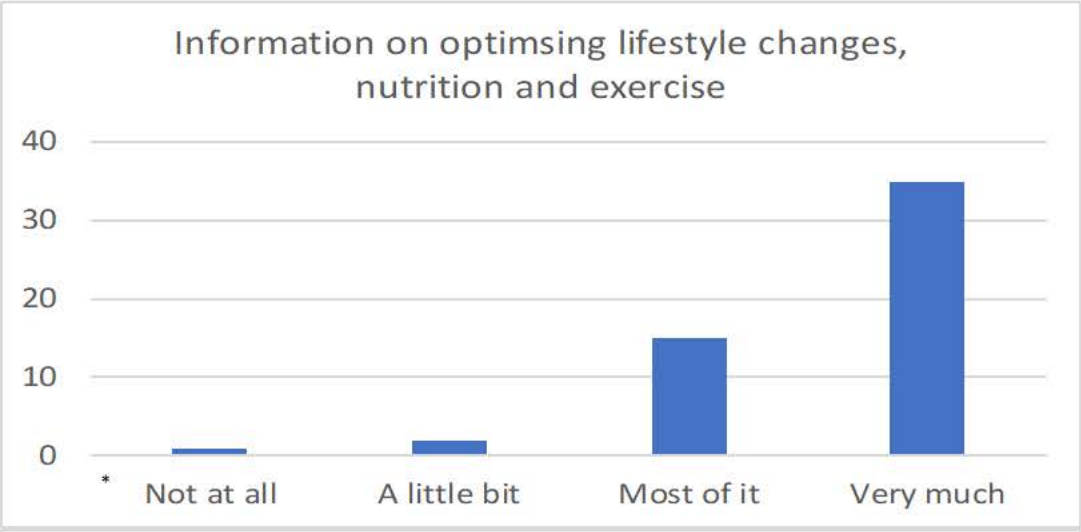

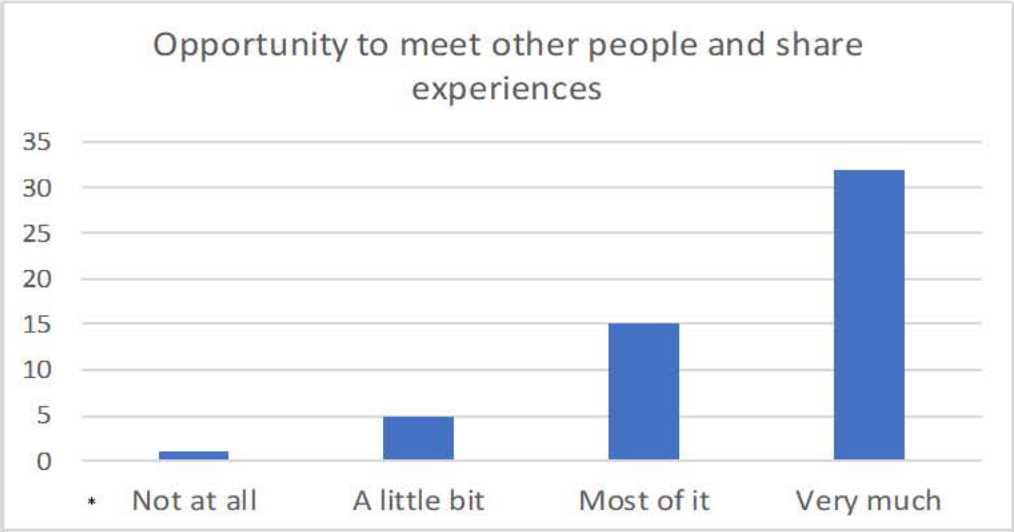

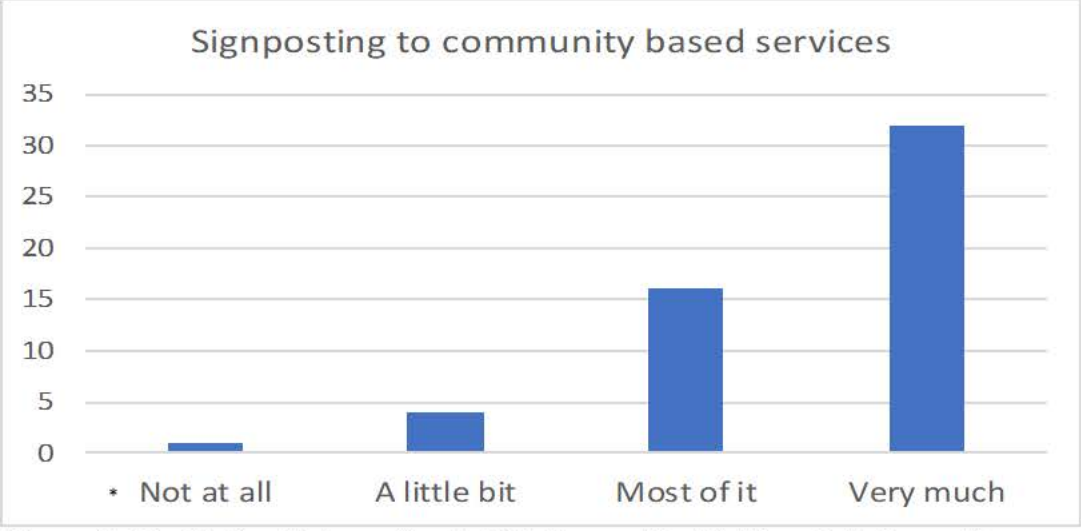

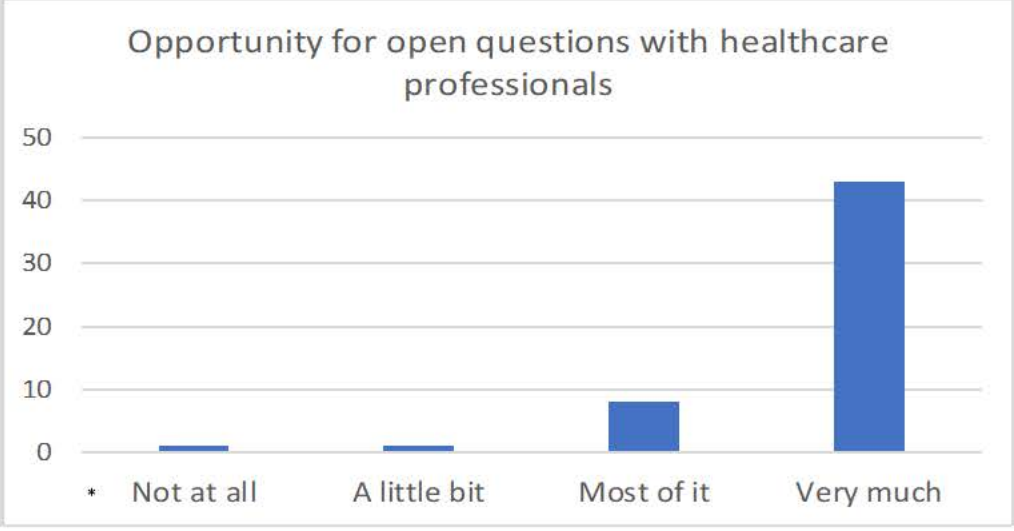

Figure 2. Qualitative Data on Pre-Habilitation on the Multimodal Intervention.
*I found the information on this subject helpful and informative

Table Prevalence of Unmet Supportive Care Needs Experienced by Patients Prior to Radical Prostatectomy (SCNS-SF34 Questionnaire)

Domains of Unmet Supportive Care Needs	Low Unmet need. I had Little Need for Additional Help. N (%)	Moderate Unmet Need. I had Some Need for Additional Help. N (%)	High Unmet Need. I had Strong Need for Additional Help. N (%)
1.Pain	**0 (0%)**	**1 (2.7%)**	**0 (0%)**
2.Lack of energy/tiredness	**3 (8.1%)**	**0 (0%)**	**1 (2.7%)**
3.Feeling unwell a lot of the time	**3 (8.1%)**	**0 (0%)**	**1 (2.7%)**
4.Work around home	**0 (0%)**	**0 (0%)**	**0 (0%)**
5.Not being able to do the things that you used to do	**2 (5.4%)**	**0 (0%)**	**0 (0%)**
6.Anxiety	**6 (16.2%)**	**0 (0%)**	**1 (2.7%)**
7.Feeling down or depressed	**6 (16.2%)**	**2 (5.4%)**	**0 (0%)**
8.Feelings of sadness	**3 (8.1%)**	**1 (3.0%)**	**2 (5.4%)**
9.Fear about the cancer spreading	**3 (8.1%)**	**5 (13.5%)**	**0 (0%)**
10.Worry that the results of treatment are beyond your control	**2 (5.4%)**	**1 (2.7%)**	**2 (5.4%)**
11.Uncertainty about the future	**5 (13.5 %)**	**3 (8.1%)**	**1 (2.7%)**
12.Learning to feel in control of your situation	**5 (13.5%)**	**3 (8.1%)**	**0 (0%)**
13.Keeping a positive outlook situation	**2 (5.4%)**	**0 (0%)**	**2 (5.4%)**
14.Fear about death and dying	**1 (2.7%)**	**2 (5.4%)**	**1 (2.7%)**
15.Changes in sexual feelings	**5 (13.5%)**	**3 (8.1%)**	**1 (2.7%)**
16.Changes in sexual relationships	**4 (10.8%)**	**5 (13.5%)**	**1 (2.7%)**
17.Concerns about the worries of those close to you	**2 (5.4%)**	**4 (10.8%)**	**0 (0%)**
18.More choice about which cancer specialist to see	**1 (2.7%)**	**0 (0%)**	**0 (0%)**
19.More choice about which hospital you attend	**0 (0%)**	**0 (0%)**	**0 (0%)**
20.Reassurance by medical staff that the way you feel is normal	**0 (0%)**	**0 (0%)**	**0 (0%)**
21.Hospital staff attending promptly to your physical needs	**0 (0%)**	**0 (0%)**	**0 (0%)**
22.Hospital staff acknowledging, and showing sensitivities to your emotional needs	**0 (0%)**	**0 (0%)**	**0 (0%)**
23.Being given written information about the important aspects of your care needs	**1 (2.7%)**	**0 (0%)**	**1 (2.7%)**
24.Being given information (written diagrams, drawings) about managing your illness and side-effects at home	**1 (2.7%)**	**0 (0%)**	**1 (2.7%)**
25.Being given explanations for those test for which you would like explanations	**0 (0%)**	**1 (2.7%)**	**0 (0%)**
26.Being adequately informed about the benefits and side-effects of treatment before you choice to have them	**0 (0%)**	**0 (0%)**	**0 (0%)**
27.Being informed about test results as soon as feasible	**1 (2.7%)**	**0 (0%)**	**0 (0%)**
28.Being informed about cancer that is under control or diminishing	**0 (0%)**	**0 (0%)**	**0 (0%)**
29.Being informed about the things that you can do to get well	**2 (5.4%)**	**0 (0%)**	**1 (2.7%)**
30.Having access to professional counselling	**1 (2.7%)**	**0 (0%)**	**1 (2.7%)**
31.Being given information about sexual relationships	**1 (2.7%)**	**0 (0%)**	**0 (0%)**
32.Being treated like a person not just another case	**0 (0%)**	**0 (0%)**	**0 (0%)**
33.Being treated in a hospital or clinic that is physically pleasant as possible case	**0 (0%)**	**0 (0%)**	**0 (0%)**
34.Having one member of hospital staff with whom you can talk to	**0 (0%)**	**0 (0%)**	**1 (2.7%)**